K061955 (pg 1 of 2)

510(K) SUMMARY

1. SUBMITTER:

AUG - 4 2006

Creative Medical Designs, Inc.
13914 Shady Shores Drive
Tampa, FL 33613
813 - 875-9999 (phone)
813-961-5543 (fax)

Contact: Jane Rayhack, CEO
Date Prepared: July 6, 2006

2. DEVICE:

Trade Name: Rayhack^{R} Low Profile Locking Plate and Instruments
Common Name: Bone Fixation Plate
Class: II
Classification Name: Single/multiple component bone fixation appliances and accessories Fastener, Fixation, non-degradable soft tissue

3. PREDICATE DEVICE:

Rayhack Osteotomy System (K952766)

4. DEVICE DESCRIPTION:

The Rayhack^{R} Low Profile Locking Plate and Instruments is an implant intended for fixation of long bones to assist healing. The implant is fabricated from stainless steel. It is fixated with two 2.7mm locking screws, four 3.5mm standard cortical screws and one 2.7 standard interfragmentary cortical screw. In addition to the plate and screws, there are instruments intended to assist with the procedure.

5. INTENDED USE:

The Rayhack^{R} Low Profile Locking Plate is a metallic surgical implant intended for long bone fixation utilized to assist healing but not intended to replace normal body structures. The plate and screws which attach to the bone are temporary internal fixation devices which align the bone surfaces in order to permit bone healing.

6. COMPARISON OF CHARACTERISTICS:

The proposed Rayhack^{R} Low Profile Locking Plate is fabricated from identical materials as the predicate device. In addition, the plate and instrumentation is

essentially identical to the predicate except it allows for the use of locking screws and the plate is a lower profile. Instrumentation has been modified to work with the revised plate.

7. PERFORMANCE DATA:

The following performance data was proved in support of the substantial equivalence determination:

Bone Model Testing: The holding strength and stiffness characteristics of the new plate compared to the predicate plate.

The testing demonstrates substantially equivalent performance between the two devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2006

Creative Medical Design, Inc.
% Ms. Jane Rayhack
CEO
13914 Shady Shores Drive
Tampa, Florida 33613

Re: K061955
Trade/Device Name: Rayhack® Low Profile Locking Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: July 10, 2006
Received: July 11, 2006

Dear Ms. Rayhack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061955

Device Name: Rayhack^{R} Low Profile Locking Plate

Indications for Use:

The Rayhack^{R} Low Profile Locking Plate is a metallic surgical implant intended for long bone fixation utilized to assist healing but not intended to replace normal body structures. The plate and screws which attach to the bone are temporary internal fixation devices which align the bone surfaces in order to permit bone healing.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Page __ of ___

Division of General, Restorative, and Neurological Devices

(Posted November 13, 2003)

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